

## **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-3 and 5-21 are now pending in this application. The element of original claim 2 has been inserted into claim 1. The range of original claim 2 has been amended; support for this lower limit can be found in the specification, e.g. see paragraph [0011] of the publication of this application. New claims 16-20 define alternative embodiments of the invention and correspond to the elements described in claims 3, 5 and 10-12 respectively. The element of claim 21 is support in the specification, see e.g. paragraph [0014] of the publication of this application. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112.

### **II. THE 35 U.S.C. 112, 2<sup>nd</sup> PARAGRAPH REJECTION HAS BEEN OVERCOME**

Claims 2, 14 and 15 were rejected as allegedly failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Reconsideration of these rejections is requested in light of the amendments made to the claims.

The range of original claim 2 has been inserted in to claim 1 which is believed to address the rejection of claim 2.

The “preferably” language of claims 14 and 15 has been deleted which is believed to address the rejection of claims 14 and 15.

### **III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

**A. Claims 1, 2, 4, 6, 7, 9 and 13-15 were rejected as allegedly being obvious over Becher (U.S. Patent 6,153,222) in view of Zerbe et al. (U.S. Patent 6,177,096 – “Zerbe”).**

**B. Claims 3 and 5 were rejected as allegedly being obvious over Becher (U.S. Patent 6,153,222) in view of Zerbe et al. (U.S. Patent 6,177,096 – “Zerbe”), further in view of Mulye (U.S. Patent 6,946,146).**

**C. Claims 1, 2, 6-9 and 13-15 were rejected as allegedly being obvious over Becher**

(U.S. Patent 6,153,222) in view of Lydzinski et al. (U.S. Patent Application Publication 2003-0099692 – “Lydzinski”).

As these rejection all utilize the Becher reference as a primary reference, the response to the above rejections are addressed collectively below.

When making the determination of obviousness, both the applicants' claimed invention and the cited references must be considered as a whole.

The applicants' claimed invention is clearly directed toward a dosage form in film form for surface administration. Moreover, the film form of claim 1 has 20% to 60% by weight of glycerol as plasticizer. As noted in the applicants' specification, the state of the art for these types of dosage forms was that in order to have proper elasticity, softness and flexibility, the amount of plasticizers employed was up to 20% by weight based on the amount of polymer (see paragraph [0008] of the publication of this application).

One of ordinary skill in the art would have expected that using greater amounts of plasticizers would have resulted in phase separations due to crystallization resulting in films which are not transparent and/or having the plasticizer separate out of the film (see paragraph [0009] of the publication of the application).

***Becher and Zerbe do not contradict the state of the art with respect to plasticizers***

With respect to Becher, there is nothing within the specification which would contradict the state of the art presented by the applicants in their application. Becher does not refer to the use of plasticizers (the term is nowhere to be found in Becher). Becher does refer to glycerol as a softener under the heading of “Further Substances”, but one of ordinary skill in the art would not have considered glycerol to be a required element of the invention or that using 20% or more of glycerol would not have resulted in phase separations due to crystallization.

The Zerbe reference does not remedy the deficiencies of Becher and is directed to a different invention, i.e. Becher's polymers are crosslinked, but Zerbe's are not. As such, there was no reasonable expectation of success that the amount of plasticizer used by Zerbe would have been applicable to the invention of Becher especially when both Becher and Zerbe refer to plasticizers as being optional elements.

Mulye is relied upon only for the teaching of a polymeric film and Lydzinski is relied upon only for the teaching of the use of different active ingredients and as such do not remedy the deficiencies of the combination of Becher and Zerbe as applied to claims 1, 2, 4, 6, 7, 9 and 13-15.

Therefore, the applicants claims are unobvious over any combination of Becher, Zerbe, Mulye and/or Lydzinski as elements of the applicants claimed dosage form are not taught to be used in combination.

***Applicants have shown evidence of unexpected results***

Consideration of obviousness also requires a consideration of any evidence of unexpected results. For the presently claimed invention, a required element of the invention is that the plasticizer is glycerol. Whereas the embodiments of the applicants claimed invention using glycerol as plasticizer show easy handleability and applicability to the human skin and mucous membrane, this was not true of comparative examples where no plasticizer was used (Comparative Example 1) or alternative plasticizers were used (polyethylene glycol (Comparative Example 2); sorbitol (Comparative Example 3); and triethyl citrate (Comparative Example 4)).

As such, the applicants claims are also unobvious because the applicants have surprisingly shown that the specific use of glycerol as a plasticizer allows one of ordinary skill in the art to be able to use more plasticizer than was previously thought possible by those of skill in the art.

**D. Claims 1, 2, 4 and 6-15 were rejected as allegedly being obvious over Carli et al.** (U.S. Patent 5,582,836 – “Carli”) in view of Lydzinski et al. (U.S. Patent Application Publication 2003-0099692 – “Lydzinski”).

The claims were alternatively rejected over Carli and Lydzinski, but this is essentially a duplicate rejection of Becher and Zerbe with the same attendant problems, i.e. Carli refers to a cross-linked dosage form whereas Lydzinski does not (uses starch products) and does not contradict the state of the art with respect to the use of plasticizers.

Carli is an even weaker reference as not only does it fail to mention the use of plasticizers, it also fails to even mention the use of glycerol in any context. Moreover, there is

no evidence that Lydzinski' reference to "any desired amount" would have been in amounts greater than that thought possible by those of skill in the art (the fact that Lydzinski referred to ranges consistent with the state of the art, i.e. 0 to 15% and 0 to 10%, suggests otherwise) or that Lydzinski's ranges would have been applicable to crosslinked hydrophilic polymers.

In addition, the combination of Carli and Lydzinski does not teach the unexpected results which are achieved by the specific use of glycerol as a plasticizer.

Therefore, the combination of Carli and Lydzinski also does not render the applicants claimed dosage form to be obvious.

### **CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
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